## REMARKS

Claims 1-8 were originally pending in this application. Claim 8 was withdrawn from consideration in view of a Restriction Requirement. New claims 9-13, based upon the original claims and the teachings of the original specification were added in the last response. Claim 2 has been amended and new Claim 14 has been added directed to subject matter previously recited in Claim 2. Claim 1 has been voluntarily cancelled herein. Applicant reserves the right to file one or more appropriate continuing applications for the subject matter of the cancelled claims. Now the pending claims are 2-7 and 9-14.

Claim Objections:

Claims 2 and 3 are objected to because of the following informalities: The claims should only have one period in a claim. In view of the amendments made herein, this objection may now be withdrawn. Such action is respectfully requested.

Claim Rejections - 35 U.S.C. § 103:

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller US 5,129,824 (`824) in view of Hill US 5,993,784 (784) and Kim et al US, 6,045,800 (`800). This rejection is respectfully traversed for the following reasons:

A critical step in analyzing the patentability of claims pursuant to Section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where

the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Most if not all inventions arise from a combination of old elements. See *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). Thus, every element of a claimed invention may often be found in the prior art. *Id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *Id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making **the specific combination** that was made by the applicant. See *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). That is the situation here. The art recognized aspects of the present invention, but failed to teach or suggest the specific combination made by the Applicant. Specifically:

(1) Keller:

Keller teaches a method for the treatment of periodontal disease, that is supposed to be conducted by the patient – but in reality is not, particularly due to the required "self" use of a syringe - for the injection of the tetracycline antibiotic into the gum tissue. This is not something that should be tried at home without the aid of another person – and preferably, a trained dental professional. See the Examples of the Keller patent, which show that the injection was a necessary step of successful treatments.

As taught therein, it is clear that Keller neither teaches nor suggests the present invention:

> In accordance with the objectives, generally stated, there is provided a method of treatment of periodontal diseases comprises the delivery of a medicament in close proximity to the bone and supporting structure of the teeth.
>
> ***The medicament is preferably forcibly delivered directly to the infected site by flossing, brushing, or injection through the use of tufted floss, an interdental brush or syringe, respectively, or by hydrostatic or mastication pressure through the use of a tray appliance or the like.*** Preferably, the flossing or brushing application is carried out using a piece of floss or an interdental toothbrush which carries a supply of the medicament. The floss preferably has tufted section which enhances the carrying capability of the floss. The application of medicament by floss or interdental toothbrush may be supplemented by application of the medication in a flexible tray appliance molded of a suitable synthetic resin material or elastomeric material to conform to the patient's teeth so as to fit closely on the teeth and supporting structure.
>
> Preferably, the medicament used with the floss or brush delivery device is an antibiotic, such as a tetracycline solution. The medicament used with the tray delivery device is preferably a combination of a tetracycline solution and a hydrogen peroxide (oxygenator) gel such that as the hydrogen peroxide decomposes into oxygen and water within the gap between the patient's teeth and the form fitted tray, the antibiotic is forced by hydrostatic pressure beneath the gingiva directly to the infected site. The oxygen rich environment within the tray appliance resulting from the decomposition of the hydrogen peroxide decreases the activity of anaerobic microorganisms in the gingiva area. Antiplaque medications may also be used to decrease plaque build-up.

The Keller methodology is a drastic one – not a simple routine that a person would readily practice at home. In addition, Keller teaches nothing about the use of soft abrasives as claimed herein.

(2) Hill:

Hill teaches cleaning the gingival tooth surfaces with a grooved and ribbed toothbrush, which is designed to hold low foaming toothpastes containing an abrasive therein.

In order for the abrasives used in toothpastes today to approach optimum cleaning abrasion performance, channeled bristle toothbrushes have been developed to entrap the abrasive and extend abrasive/toothbrush contact beyond tangential contact between bristle tips/abrasive with tooth surfaces. Preferred brushes of this type are described in U.S. application Ser. No. 08/899,679.

ABRASIVE

The therapeutic toothpaste compositions of the present invention contain from between about 1% and about 90%, preferably from between about 10% and 50% by weight, of an abrasive material described in detail below. These abrasives in the low foaming dentifrices of the present invention provide the unique abrasion benefits of exceptionally efficient cleaning, i.e. CEC values above about 1.1 along with exceptional polishing, stain removal and abrasion as indicated by AEC values of at least about 1.1. The exceptional AEC values are obtained without unduly abrading tooth enamel or dentin.

Suitable abrasive materials for the low foaming therapeutic toothpastes of the present invention include: talc, calcium pyrophosphate, calcium hydrogen phosphate dihydrates, anhydrous dicalcium phosphate, calcium carbonate, alumina, tin dioxide, silica, zirconium silicate, sodium bicarbonate, sodium percarbonate, etc., and mixtures thereof. Particularly preferred are abrasive mixtures where the secondary abrasive is the type used in translucent dentifrice gels at levels up to about 20%. Some of these are described in U.S. Pat. No. 3,927,200; 3,906,090, 3,937,321; 3,911,102; 4,036,949; 4,891,211; 4,547,362; 5,374,368; 5,424,060; 5,180.576; 4,943,429; 4,160022; 4,623,536; 4,663,153; and 4,721,614.

Other useful abrasives include: sodium metaphosphate, potassium metaphosphate, magnesium orthophosphate, trimagnesium phosphate, alumina silicate and hetonite as described in U.S. Pat. No. 4,806,340 incorporated herein by reference. See also Thorpe's Dictionary of Applied Chemistry, Volume 9, 4th Edition, pp. 510-511.

Particularly preferred abrasives that are compatible with sources of soluble fluoride include those precipitated silica or silica gels such as the silica xerogels described in U.S. Pat. No. 3,538,230 incorporated herein by reference. Preferred are the silica/xerogels marketed under the tradename Syloid by W. R. Erecex Co., Davison Chemical Division. Especially preferred are the precipitated silica materials such as those marketed by the J. M. Huber Corporation under the tradename Zeodent, particularly the silica carrying the designation Zeodent 119. Other silica dental abrasives useful in the toothpastes of the present invention are disclosed in U.S. Pat. No. 3,862,307 and 4,340,583 incorporated herein by reference.

Other abrasives useful in the low foaming therapeutic dentifrice compositions of the present invention include calcium pyrophosphate including the B-phase calcium pyrophosphate prepared in accordance with the teaching of U.S. Pat. No. 3,112,247 incorporated herein by reference. Another class of abrasives suitable for use with the low foaming toothpastes of the present invention include particulate thermosetting polymerized resins as described in U.S. Pat. No. 3,0750,510 including melamines, phenolics, ureas, melamine-ureas, melamineformaldehydes, urea-formaldehydes, melamine-urea-formaldehydes, cross-linked epoxides and cross linked polyesters. See also U.S. Pat. No. 4,070,510 incorporated herein by reference.

The size of the abrasive particles are most commonly expressed in "mean diameter", i.e. the arithmetical average of the diameters of particles in a representative sample. The mean diameter value of abrasive particles is usually described in microns. Abrasives having particle sizes between about 3 and 25 microns and preferably between about 6 and about 20 microns are particularly preferred for the channel designs of the toothbrush bristles of the present invention.

The preparation of suitable particle size abrasives can be accomplished by conventional techniques well known to the art. Basically, these techniques involve milling various abrasive materials, followed by standard screen sieving (or air separation) to segregate the desired particle size range. Other techniques employ crystallization or related techniques to control size and crystal variants.

Nothing in Hill teaches or suggests the presently claimed invention, which is a self-treatment process for periodontal patients with gingival detachment of about 3 mm and greater, comprising the step of physically removing biofilms on a daily basis from supragingival, interproximal and subgingival tooth surfaces and simultaneously

controlling inflammation related substances associated with heart disease by administering soft abrasives thereto – as set forth in Claim 2.

More importantly, nothing in Hill provides any motivation for a combination the specific teachings therein with any of the teachings of the Keller patent. Both patents are directed to very specific methods and devices. Keller relies upon syringe delivery of tetracycline for successful treatment of periodontal diseases, while Hill uses a novel toothbrush design for efficient cleaning of tooth surfaces – without mention of the treatment thereby of periodontal diseases. The skilled artisan would simply not be motivated to combine these two patents in the manner suggested by the Examiner.

(3) Kim:

Finally, Kim teaches compositions for preventing or treating periodontal diseases comprising extract from *Achyranthis radix* or *Ulmus cortex*. Specifically:

> The present invention provides a composition for preventing or treating periodontal diseases comprising an extract of Achyranthis radix, Ulmus cortex or a mixture thereof which inhibits the productions of superoxide, prostaglandin, and interleukin (IL-1.beta.) which are inducers for periodontal diseases and inhibits the enzyme activity of collagenase which decomposes collagen protein which is a substrate for the periodontal tissues, and at the same time promotes collagen protein synthesis, thereby treating periodontal diseases efficiently.
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> Accordingly, the inventors have conducted an extensive research for many years in order to develop a drug which has no toxic side-effect while shows excellent therapeutic effects on the periodontal diseases even if it is administered to human for a long time, making the various Chinese herbal medicines and plant extracts an object of research by means of scientific methods such as the activity determination for collagenase which decomposes the periodontal tissues, the quantitative analysis of interleukin-1.beta. and prostaglandin ($PGE_2$) which cause the periodontal diseases, the determination of the superoxide production and the quantitative analysis for collagen synthesis, and have screened Chinese herbal medicines and plant extracts which have excellent

effects on inhibiting the activity of collagenase or inhibiting the productions of interleukin-1.beta. and prostaglandin while promote the collagen synthesis. As a result, the inventors have discovered that the specific extract of Achyranthis radix or Ulmus cortex as described below has excellent effects on inhibiting the production of the periodontal disease-inducing agents and at the same time on inhibiting the activity of the periodontal tissue-decomposing enzyme for periodontal tissues and on promoting the collagen synthesis, and have completed the present invention.

Nothing in Kim teaches or suggests the presently claimed invention, which is a self-treatment process for periodontal patients with gingival detachment of about 3 mm and greater, comprising the step of physically removing biofilms on a daily basis from supragingival, interproximal and subgingival tooth surfaces and simultaneously controlling inflammation related substances associated with heart disease by administering soft abrasives thereto – as set forth in Claim 2.

More importantly, nothing in Kim provides any motivation for a combination the specific teachings therein with any of the teachings of the Keller or Hill patents. These three patents are directed to very specific methods and/or devices. Keller relies upon syringe delivery of tetracycline for successful treatment of periodontal diseases, while Hill uses a novel toothbrush design for efficient cleaning of tooth surfaces – without mention of the treatment thereby of periodontal diseases. Kim adds Chinese herbal medicines and plant extracts for the treatment of periodontal diseases. The skilled artisan would simply not be motivated to combine these patents in the manner suggested by the Examiner.

Moreover, even if such a combination was made – the resulting teaching would not be the invention claimed by the Applicant. Instead, the combined teaching would still require the syringe application of tetracycline (Keller), with the use of a channel/ribbed toothbrush for application of low foaming toothpaste (Hill), and further include the Chinese herbal medicines and plant extracts of Kim. This combination of teachings is

not claimed herein – and thus, the Section 103 rejection of the pending claims should be reconsidered and withdrawn. Such action is respectfully requested.

## FEE AUTHORIZATION

Please charge any fees due in connection with this filing to Deposit Account No. 19-0733.

## CERTIFICATE OF FACSIMILE TRANSMISSION

The undersigned hereby certifies that this correspondence was submitted by facsimile in the USPTO on the date shown on Page 1.

Respectfully submitted,

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